

REMARKS

In response to the Office Action of October 17, 2003, applicants respectfully request reconsideration and allowance of the claims in their amended form.

By this amendment applicants have deleted a sentence on page 1 of the specification which was a repetition of the preceding sentence. Any inconvenience to the Examiner is sincerely regretted.

Applicants have also amended the claims to a form which is believed to clearly distinguish over the disclosure and teachings of the prior art.

Applicants have carefully reviewed the rejection of claims 1-5, 8,9, 12-16 and 19-20, as being anticipated under 35 USC102(b) or obvious under 35USC103(a) over the patent to Zimmerle, U.S. 5,403,744.

Zimmerle discloses and claims a method, composition and device for measuring the ionic strength or specific gravity of a test sample. The tests in question can include tests for diabetes insipidus glomerulonephritis, pyelonephritis, and various other renal abnormalities. In these conditions the kidney has lost its ability to concentrate urine because of tubular damage (column 2, lines 1-4).

Hence, Zimmerle is directed to a more complex and quantitatively accurate test which in its preferred aspects requires using a reagent composition which interacts with metal cations in a test sample to produce a detectable and measurable response that can be correlated to the ionic strength or specific gravity of the test sample. At column 8, lines 3-16, Zimmerle states that his method utilizes a new reagent composition which includes (1) a metachromatic dye that may, or may not be sensitive to pH changes, or a combination of a metachromatic dye and a pH indicator dye, and (2) a strong polyelectrolyte buffered at a pH of about 3 or less.

In contrast to the Zimmerle reference which discloses a more accurate, quantitative method for the determination of ionic strength and/or specific gravity of an aqueous test sample, the present invention is directed to a simple, qualitative method for the immediate determination of whether a person, particularly one who is currently engaged in sports or other strenuous activity, is dehydrated or not. This person can in the privacy of a rest room or other discrete place, can by simply urinating onto the device of the present invention, instantaneously find out whether he or she is dehydrated or not. Hence, the present invention is directed to a very simple device which can be hand-held by either male or female and in a few seconds note whether a color change occurs on the device after urinating onto the lower end. The device of this invention is similar to the hand-held device that women use to determine pregnancy.

In contrast, the invention disclosed in Zimmerle is a more complex and accurate method for the determination of ionic strength or specific gravity of a test sample. The reference is silent as to the source of the sample being tested. While it is stated at column 1, lines 51-58, that a first morning urine sample may be tested in both a laboratory or at home, there is nothing in the reference which discloses or suggests that the Zimmerle device is one upon which the user merely urinates which holding the device in ones hand and obtain an immediate color change which can be compared with a color chart present on the handle as in the instant invention.

While Zimmerle may disclose at column 7, lines 59-63, a filter paper impregnated with a novel reagent composition, (column 8, line 6), and also discloses (column 23, lines 58-60) that the filter paper can be secured to a handle, it only discloses that the filter paper test strip can be dipped into a fresh urine sample for a sufficient time to saturate the test pad with the sample. Moreover, there is no indication that a color chart is affixed to the handle for immediate comparison of the color change.

Accordingly, it does not appear that Zimmerle ever contemplated a portable device that does not require dipping into a previously obtained sample, and which could easily be used at most any location where one could urinate in privacy onto a device and obtain a reading as to the person's dehydration status.

Zimmerele evidently contemplated that his method would be used in the confines or a laboratory or if used at home, by first obtaining a sample and then wetting the filter paper attached to a handle by dipping into a sample.

In order to more clearly distinguish their invention over the Zimmerle reference, applicants have amended their claims in a manner which should place them in condition for allowance. The claims as amended now recite that the device is comprised of plastic and has the color chart located on the upper portion of the handle. Also, the chemicals at the lower portion of the device are in the dry form.

Zimmerele's disclosure and claims all indicate the chemical composition that is used to undergo a color change is comprised of the dyes and a carrier that is water, a water miscible alcohol or a mixture thereof. Moreover, Zimmerle does not disclose that the composition is dried on the filter paper nor that the color chart can be placed on the same device which holds the filter paper. Moreover, it should be noted that the Zimmerle composition is buffered to a pH of 3 or less, which is acidic, whereas in the present invention the formulation contains over 28 percent of sodium hydroxide, a base.

Accordingly, applicants respectfully submit that under 35USC102(b), Zimmerle does not disclose each and every element of their invention as presently claimed. Zimmerle does not disclose that applicants' invention is a hand-held, throw-away upon which the user can direct a stream of urine and the color change compared with a color chart displayed on the handle.

Moreover, Zimmerle does not contemplate urinating directly onto the filter paper containing the chemical composition. Additionally, his composition contains a metachromatic dye which may or may not be pH sensitive. In contrast, applicants' invention only uses a dye which changes with pH. Applicants wish to emphasize that their invention is a very simple one for the qualitative determination of ones dehydration status. Zimmerle is a much more complex invention for the quantitative determination of ionic strength as well as specific gravity and is useful for determination of several medical conditions.

Applicants also respectfully submit that their invention would not have been obvious under 35USC103(a) at the time their invention was made in view of the teachings of Zimmerle. One of ordinary skill in the art who had never seen the present invention, upon reading the reference would find not incentive or suggestion to prepare the simple device as presently claimed. By the present invention, applicants have provided a simple device and method whereby a person engaged in sports or strenuous exercise can easily and quickly determine his or her own dehydration status. Withdrawal of the rejection of the claims over the Zimmerle reference is therefore respectfully requested.

Applicants have carefully reviewed the Falb et al reference (US 4,318,709) cited by the Examiner to show the state of the art and respectfully submit that the reference does not disclose nor render obvious the present invention.

Applicants therefore submit that a *prima facie* case of obviousness has not been made over the Zimmerle reference. There is no "fair suggestion" of applicants' invention under 35USC103(a). Applicants respectfully submit that one must not lose sight of the statutory provisions under which patents are granted to inventors to protect their discoveries. Section 102 of Title 35

indicates that the right of an inventor to a patent is a positive one; that is, the inventor shall be entitled to a patent unless one or more of the subdivisions of the section are applicable. Moreover, Section 103(a) when read in the light of the preceding section, must also be considered from the premise that an inventor shall be entitled to a patent unless the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. Hence, the invention in question must be obvious to from the reference to that person who has ordinary skill and who is unaware of and has no knowledge of applicants' discovery. In other words, applicants' invention must manifest itself, or stand out from the teachings of the reference. It must not be hidden in the teachings thereof, only to be uncovered by one who is viewing the art with the knowledge already gleaned from applicants' application.

While it is often possible to select from the prior elements which will approximate the invention shown in the application, the fact that such selection can be made does not necessarily preclude the presence of a patentable invention. The test to be given to determine whether an invention is obvious is the "fair suggestion" test. The basic reason for the fair suggestion test is based on the fact that the Examiner has had the opportunity to consider and digest applicants' disclosure prior to searching the art. As such it is relatively easy to unintentionally hold that the reference teaches the invention under consideration. (In re Lunsford, 148 USPQ 721).

For each of the foregoing reasons applicants submit that the claims in their amended form are in condition for allowance. Early, favorable action is respectfully requested.

Respectfully submitted

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